MAY 2 8 2002

K021380
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BIOMET
CORPORATE HEADQUARTERS

Summary of Safety and Effectiveness

Applicant/Sponsor: Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Patricia Sandborn Beres
Biomet Orthopedics, Inc.
56 Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587
Phone: (574) 267-6639 extension 1278
Fax: (574) 372-1790

Proprietary Name: OSS Les Proximal Femoral Component

Classification Name: Prosthesis, Hip, semi-constrained, metal/polymer, cemented (888.3350) and Prosthesis, Hip, semi-constrained, metal/polymer, uncemented (888.3358) – when used as proximal femoral

Legally Marketed devices to Which Substantial Equivalence is Claimed: Proximal Femoral Components previously cleared in 510(k) K002757 for the Oncology Salvage System.

Device Description: The OSS Les Proximal Femoral Component is designed for use with Biomet's Oncology Salvage System. It may be used either for proximal femoral replacement with a diaphyseal segments and intramedullary stem or as part of a total femur replacement with a segmental distal femur component and the appropriate hinged knee components.

The OSS Les Proximal Femoral Component combines features of the three styles of Proximal Femoral Components contained in 510(k) K002757.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
219.267.6639

FAX
219.267.8137

E-MAIL
biomet@biomet.com

Indications For Use: The OSS Les Proximal Femoral Component is indicated for treatment of patients that require proximal femoral, or total femur replacement for one of the following:

1) Painful and disabled joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis or traumatic arthritis
2) Correction of varus, valgus or post traumatic deformity
3) Correction of revision of unsuccessful ostoetomy, arthrosis, or previous joint replacement
4) Ligament deficiencies
5) Tumor resections
6) Treatment of non-unions, femoral neck and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques
7) Revision of previously failed total joint arthroplasty
8) Trauma

Summary of Technologies: The materials, surface finishes, and processing of the OSS Les Proximal Femoral Component are similar to the predicate devices.

Non-Clinical Testing: Engineering analysis has shown the modified device to have similar characteristics to predicate devices and no new risks are envisioned.

Clinical Testing: None provided

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 8 2002

Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, IN 46581-0587

Re: K021380
Trade Name: OSS Les Proximal Femoral Component
Regulation Number: 21 CFR 888.3350 and 888.3358
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: JDI and LPH
Dated: April 24, 2002
Received: May 1, 2002

Dear Ms. Sandborn Beres:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021380

Device Name: OSS Les Proximal Femoral Component

Indications For Use:

The OSS Les Proximal Femoral Component is indicated for treatment of patients that require proximal femoral, or total femur replacement.

Indications:
1) Painful and disabled joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis or traumatic arthritis
2) Correction of varus, valgus or post traumatic deformity
3) Correction of revision of unsuccessful ostoetomy, arthrosis, or previous joint replacement
4) Ligament deficiencies
5) Tumor resections
6) Treatment of non-unions, femoral neck and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques
7) Revision of previously failed total joint arthroplasty
8) Trauma

This device is a single use implant.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

Over-The-Counter Use

(Optional Format 1-2-96)

510(k) Number K021380